

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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STATE OF NEW YORK, STATE OF ILLINOIS, STATE OF	:	ECF CASE
MARYLAND, STATE OF WASHINGTON,	:	
Plaintiffs,	:	07-CV-8621 (PAC) (RLE)
	:	
- against -	:	REPLY
	:	DECLARATION OF
UNITED STATES DEPARTMENT OF HEALTH AND	:	JOHN M. SCHWARTZ
HUMAN SERVICES,	:	
	:	
Defendant.	:	

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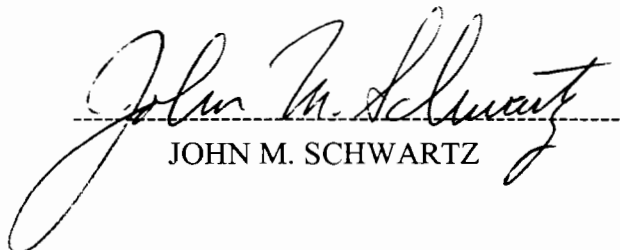
JOHN M. SCHWARTZ hereby declares the following to be true and correct under penalty of perjury, pursuant to 28 U.S.C. § 1746:

1. I am an Assistant Attorney General in the Office of Andrew M. Cuomo, Attorney General of the State of New York, the attorney for Plaintiff New York State in this action. I submit this declaration in further support of Plaintiffs' Motion for Partial Summary Judgment.
2. Annexed hereto as Exhibit A is a true and correct copy of a letter dated April 17, 2008, from Gary Kepplinger, Esq., General Counsel of the United States Government Accountability Office, to Senator John D. Rockefeller, IV, Chairman of the Subcommittee of Health Care of the Committee on Finance of the United States Senate and to Senator Olympia Snowe, a member of the Committee on Finance ("the GAO Letter"). This letter was released to the public by Senator Rockefeller and Senator Snowe on April 18, 2008, two days after the Plaintiff States in this action filed their papers in opposition to Defendant's Motion to Dismiss and in support of their Motion for Partial Summary Judgment.
3. Annexed hereto as Exhibit B is a true and correct copy of a Memorandum dated January

10, 2008, from Morton Rosenberg, Specialist in American Public Law of the Congressional Research Service, to Senator Rockefeller (“the CRS Memorandum”). This letter was also released to the public by Senator Rockefeller and Senator Snowe on April 18, 2008.

4. By letter dated April 21, 2008, I submitted copies of both the GAO Letter and the CRS Memorandum to this Court (Crotty, J.), with additional copies to Defendant’s counsel, and requested that they be added to the record of the present motions.

Dated: New York, New York
June 6, 2008



JOHN M. SCHWARTZ

EXHIBIT A



United States Government Accountability Office
Washington, DC 20548

B-316048

April 17, 2008

The Honorable John D. Rockefeller, IV
Chairman
Subcommittee on Health Care
Committee on Finance
United States Senate

The Honorable Olympia Snowe
Committee on Finance
United States Senate

Subject: *Applicability of the Congressional Review Act to Letter on State Children's Health Insurance Program*

By letter of February 13, 2008, you asked whether an August 17, 2007 letter issued by the Centers for Medicare & Medicaid Services (CMS) to state health officials concerning the State Children's Health Insurance Program is a rule for the purpose of section 251 of the Contract with America Advancement Act of 1996,¹ commonly referred to as the Congressional Review Act (the Review Act). The Review Act is intended to keep Congress informed of the rulemaking activities of federal agencies and provides that before a rule can take effect, the agency must submit the rule to each House of Congress and the Comptroller General.² For the reasons discussed below and more fully explained in the enclosure, we conclude that the August 17, 2007 letter is a rule under the Review Act. Therefore, it must be submitted to Congress and the Comptroller General before it can take effect.

BACKGROUND

The State Children's Health Insurance Program (SCHIP) finances health care to low-income, uninsured children whose family incomes exceed the eligibility limits under their state's Medicaid program, but who cannot afford other health insurance coverage.³ To participate in SCHIP, a state must submit a plan that describes how its program meets applicable requirements and must receive approval of the plan from

¹ Pub. L. No. 104-121, § 251, 110 Stat. 847, 868-74, *codified at* 5 U.S.C. §§ 801-808.

² 5 U.S.C. § 801(a)(1).

³ *See* 42 U.S.C. § 1397aa.

CMS.⁴ States are required to amend their plans to reflect changes in federal law, regulation, or policy, and changes in the operation of their programs, including, for example, changes in eligibility criteria or benefits.⁵

As required by law, a state plan must describe the procedures used to ensure that coverage under the plan does not substitute for coverage under group health plans, generally referred to as “crowd out.”⁶ Regulations promulgated by CMS require states to adopt “reasonable procedures” to prevent crowd out.⁷ Since CMS promulgated the regulations in 2001, states have adopted a number of different measures to prevent crowd out, which CMS has approved.

In its August 17 letter, CMS purports to clarify the statutory and regulatory requirements concerning prevention of crowd out for states wishing to provide SCHIP coverage to children with effective family incomes in excess of 250 percent of the federal poverty level (FPL) and identifies a number of particular measures that these states should adopt. The letter indicates that CMS will apply the measures to states’ proposals to cover such children, as well as to states that already cover them. According to the letter, CMS may take corrective action against states that fail to adopt the identified measures within 12 months.

SUMMARY OF ANALYSIS

The definition of “rule” in the Review Act incorporates by reference the definition of “rule” in the Administrative Procedure Act (APA), with some exceptions. Our analysis of whether the August 17 letter is a rule under the Review Act thus entails determining whether the letter is a rule under the APA and whether it falls within any of the exceptions contained in the Review Act.⁸ The APA definition of rule has been said to

⁴ 42 U.S.C. § 1397aa(b). The authority vested in the Secretary of Health and Human Services to approve and disapprove SCHIP state plans and plan amendments has been delegated to the Administrator of CMS. *State Child Health; Implementing Regulations for the State Children’s Health Insurance Program*, 64 Fed. Reg. 60882, 60895 (Nov. 8, 1999) (proposed rule).

⁵ 42 C.F.R. § 457.60.

⁶ 42 U.S.C. § 1397bb(b)(3)(C).

⁷ 42 C.F.R. § 457.805.

⁸ The Review Act excepts the following from its definition of rule: (1) rules of particular applicability, including a rule that approves or prescribes for future application rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. § 804(3). As discussed below, the letter is not a statement of particular applicability; rather, it substantially affects all states that seek to cover children with effective family incomes in excess of 250 percent of the FPL, as well as those states that already cover these children. The letter does not relate to agency management or personnel, and it does not relate to “agency organization, procedure, or practice” with no substantial effect on non-agency parties. Accordingly, we do not believe that any of these three exceptions applies to the August 17 letter.

include “nearly every statement an agency may make.”⁹ It includes three elements that are relevant here: an agency statement is a rule if it is of general applicability; of future effect; and designed to implement, interpret, or prescribe law or policy.

On its face, the August 17 letter meets these criteria. The letter is of general, rather than particular, applicability since it extends to all states that seek to enroll children with effective family incomes exceeding 250 percent of the FPL in their SCHIP programs, as well as to all states that have already enrolled such children.¹⁰ In addition, it is prospective in nature since it is concerned with policy considerations for the future rather than the evaluation of past or present conduct.¹¹ Finally, it purports to clarify and explain the manner in which CMS applies statutory and regulatory requirements to states that want to extend coverage under their SCHIP programs to children with effective family incomes above 250 percent of the FPL and seeks to promote the implementation of statutory requirements applicable to state plans. Accordingly, it is designed to implement, interpret, or prescribe law or policy.¹²

The history of the regulatory provision regarding substitution of coverage discussed in the letter lends support to our view that the letter is a rule. In the preamble to the proposed rule to implement SCHIP, CMS indicated that it could not require states to adopt any particular measures as part of the effort to prevent substitution of coverage, stating that it did not have a statutory or empirical basis for doing so.¹³ CMS confirmed this interpretation in a final rule.¹⁴ In its August 17 letter, however, CMS states that its experience and information derived from the operation of SCHIP programs have made it clear that the potential for substitution is greater at higher income levels, and states seeking to expand their SCHIP populations should implement specific strategies as “reasonable procedures” to prevent substitution of coverage (for example, a minimum

⁹ *Batterton v. Marshall*, 648 F.2d 694, 700 (D.C. Cir. 1980) (citing 5 U.S.C. § 551(4)). Section 551(4) of title 5, United States Code, defines the term “rule” in relevant part as “[t]he whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency”

¹⁰ *Cf. U.S. Dep’t of Justice, Attorney General’s Manual on the Administrative Procedure Act* 13 (1947) (the term “rule” includes statements of particular applicability applying either to a class or to a single person).

¹¹ *See Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216 (1988) (Scalia, J., concurring) (“future effect” means that agency statement will have legal consequences for the future); *see also U.S. Dep’t of Justice, Attorney General’s Manual on the Administrative Procedure Act* at 14 (rulemaking regulates the future conduct of either groups of persons or a single person and is essentially legislative in nature because it operates in the future and is primarily concerned with policy considerations, while adjudication is concerned with the determination of past and present rights and liabilities).

¹² *See A.D. Transport Express, Inc. v. United States*, 290 F.3d 761, 768 (6th Cir. 2002) (order explaining agency regulation is an interpretative rule under the APA); *Guardian Federal Savings and Loan Ass’n v. Federal Savings and Loan Insurance Corp.*, 589 F.2d 658, 664 (D.C. Cir. 1978) (agency statements that clarify laws or regulations are rules under the APA).

¹³ 64 Fed. Reg. at 60921-22.

¹⁴ *See State Child Health; Implementing Regulations for the State Children’s Health Insurance Program*, 66 Fed. Reg. 2490, 2601-05 (Jan. 11, 2001) (final rule).

1-year period of uninsurance before receiving SCHIP coverage). Thus, the letter amounts to a marked departure from the agency's settled interpretation of the governing regulation, and case law indicates that such a change may be made only by a rule.¹⁵ Moreover, the agency expressly relied on the letter to disapprove a request from the state of New York to amend its SCHIP plan to cover children with family incomes up to 400 percent of the FPL. The application of the letter to deny New York's proposed plan amendment only serves to confirm that the letter has binding effect and is, therefore, a rule.¹⁶

By letter of February 20, 2008, we requested the views of the General Counsel of the Department of Health and Human Services on whether the August 17 letter is a rule for purposes of the Review Act.¹⁷ The response from the Director of the Center for Medicaid and State Operations within CMS did not directly address that issue. CMS indicated, however, that the letter is a "general statement of policy that announces the course which the agency intends to follow in adjudications concerning compliance with requirements already set forth in regulations."

As a conceptual matter, general statements of policy would appear to fit squarely within the definition of rule in the APA since they advise the public prospectively of the manner in which an agency proposes to exercise a discretionary power or what the agency will propose as policy,¹⁸ and, in fact, courts have referred to them as rules.¹⁹ While some cases seem to suggest that general statements of policy are not rules under the APA,²⁰ the better reading of these cases, in our opinion, is that statements of policy

¹⁵ See *SBC Inc. v. Federal Communications Commission*, 414 F.3d 486, 498 (3d Cir. 2005) (if agency's present interpretation of regulation is a fundamental modification of previous interpretation, the modification can only be accomplished through notice and comment rulemaking); *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) (settled policy of an agency is binding on the agency and may be changed only through a rule); *Alaska Professional Hunters Ass'n v. Federal Aviation Administration*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999) (an agency is bound by settled interpretation given to its own regulation that agency can change only by rulemaking).

¹⁶ See *Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015, 1020-21 (D.C. Cir. 2000) (if an agency treats a pronouncement as if it were controlling, if it bases enforcement actions on the policies in the document, and if it leads private parties or states to believe it must comply with the pronouncement's terms, it is a substantive rule, not a general statement of policy); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (in subsequent administrative proceeding, agency cannot claim that prior statement of policy itself resolves contested issues).

¹⁷ In documents filed in related litigation, the Department of Justice has characterized the August 17 letter as a rule. See *New York v. United States Dep't of Health and Human Services*, No. 07 Civ. 08621 (S.D.N.Y. filed Oct. 4, 2007) (Def's Mem. Supp. Mot. Dismiss, p. 33).

¹⁸ See *U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* at 30, n.3.

¹⁹ See, e.g., *Chrysler v. Brown*, 441 U.S. 281, 301 (1979) ("the central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice' on the other"); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975) (general statement of policy is a rule directed at agency staff on how it will perform discretionary function); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (describing test for determining whether "a rule is a general statement of policy").


²⁰ See, e.g., *Sugar Cane Growers Cooperative of Florida v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002) (some agency pronouncements lack the firmness of a prescribed standard to be considered rules);

are not the type of rules for which the APA requires notice and comment procedures because they are tentative statements of future intent and by their nature do not have the force of law. Further, even if these cases are read to mean that general statements of policy are not rules under the APA, the August 17 letter does not have the characteristics of a general statement of policy identified in case law. Because the letter establishes a deadline by which “affected States” need to implement its measures or face the possibility of a corrective action by the agency, the letter evidences little, if any, of the tentativeness that is the hallmark of a policy statement.²¹ Finally, as noted above, the agency has relied on the letter to disapprove a state plan amendment, treating the letter as if it were a binding rule.

CONCLUSION

The August 17 letter from CMS to state health officials is a statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy with regard to SCHIP. Accordingly, it is a rule under the Congressional Review Act. Therefore, before it can take effect, it must be submitted to Congress and the Comptroller General.

If you have any questions concerning this opinion, please contact Dayna K. Shah, Managing Associate General Counsel, at (202) 512-8208; Helen T. Desaulniers, Assistant General Counsel, at (202) 512-4740; or Kevin C. Milne, Deputy Assistant General Counsel, at (202) 512-4586.



Gary L. Kepplinger
General Counsel

Enclosure

cc: James Stansel, Esq.
Acting General Counsel
Department of Health and Human Services

Syncor International Corp. v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997) (the primary distinction between a rule and a general statement of policy is whether the agency intends to bind itself to a legal position); *Pacific Gas and Electric Co. v. Federal Power Commission*, 506 F.2d 33, 37 (D.C. Cir. 1974) (suggesting that policy statements are not rules under the APA).

²¹ See *Pacific Gas and Electric Co.*, 506 F.2d at 36-45 (discussing the language of a “statement of policy” and noting that such a statement announces tentative intentions for the future); cf. *Community Nutrition Institute v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987) (agency prescribed standard from which regulated entities could obtain “exception” or risk enforcement action indicated standard was binding).

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B-316048

ENCLOSURE

*Applicability of the Congressional Review Act to Letter on
State Children's Health Insurance Program*

The Centers for Medicare and Medicaid Services (CMS) issued a letter dated August 17, 2007 to certain state agencies concerning the State Children's Health Insurance Program. For the reasons discussed below, we conclude that the August 17 letter is a "rule" for the purpose of section 251 of the Contract with America Advancement Act of 1996,¹ commonly referred to as the Congressional Review Act (the Review Act). Therefore, in accordance with the Review Act, the letter must be submitted to Congress and the Comptroller General before it can take effect.

BACKGROUND

The State Children's Health Insurance Program

The State Children's Health Insurance Program (SCHIP), created in 1997, finances health care to low-income, uninsured children whose family incomes exceed the eligibility limits under their state's Medicaid program, but who cannot afford other health insurance coverage.² Like Medicaid, SCHIP is financed jointly by contributions from the federal government and the states. Under Medicaid, the federal government matches a portion of each state's Medicaid expenditures according to a matching rate that is based in part on the state's per capita income relative to the national average.³ Under SCHIP, the federal government also matches a state's SCHIP expenditures, but at a rate that is generally higher than the Medicaid matching rate.⁴

To participate in SCHIP, a state must submit a state plan and must receive approval of the plan from CMS.⁵ A state plan is a comprehensive written description of the operation of the state's SCHIP program, including eligibility standards and benefits provided, in sufficient detail for CMS to determine whether the plan meets applicable

¹ Pub. L. No. 104-121, § 251, 110 Stat. 847, 868-74, *codified at* 5 U.S.C. §§ 801-808.

² *See* 42 U.S.C. § 1397aa. Medicaid finances health care for certain low-income families, children, pregnant women, elderly persons, and persons with disabilities. In general, under SCHIP, a state is allowed to cover children in families with incomes up to 200 percent of the federal poverty level or 50 percentage points above the state's Medicaid income eligibility limit as of March 31, 1997. *See* 42 U.S.C. §§ 1397jj(b)(1) and (c)(4).

³ 42 U.S.C. §§ 1396b(a), 1396d(b).

⁴ *See* 42 U.S.C. § 1397ee(a).

⁵ 42 U.S.C. § 1397aa(b). The authority vested in the Secretary of Health and Human Services to approve and disapprove SCHIP state plans and plan amendments has been delegated to the Administrator of CMS. *State Child Health; Implementing Regulations for the State Children's Health Insurance Program*, 64 Fed. Reg. 60882, 60895 (Nov. 8, 1999) (proposed rule).

requirements.⁶ The plan also assures CMS that the state will administer its program in accordance with those requirements.⁷ Regulations require states to amend their state plans whenever necessary to reflect changes in federal law, regulations, policy interpretations, or court decisions, as well as changes in the operation of their programs, including, for example, changes in eligibility criteria or benefits.⁸

States have considerable flexibility under SCHIP in structuring their programs. They may expand their existing Medicaid programs to provide coverage to children who are eligible under SCHIP. Alternatively, they may implement separate child health programs. In addition, a state may have a combination of both a separate child health program and a Medicaid expansion.⁹

State SCHIP programs are subject to a number of statutory provisions that are designed to ensure that SCHIP coverage does not become a substitute for other public or private coverage. For example, section 2102(b)(3)(C) of the Social Security Act requires that a state plan include a description of the procedures used to ensure that state SCHIP coverage does not substitute for health insurance coverage under group health plans.¹⁰ Under section 2102(c)(2) of the Social Security Act, states also must describe in their plans the procedures used to coordinate their SCHIP programs with other public and private programs.¹¹

CMS has promulgated regulations designed to implement the statutory provisions to prevent substitution of coverage.¹² Among the regulations promulgated, section 457.805 of title 42, Code of Federal Regulations, requires that a state plan include a description of “reasonable procedures” to ensure that coverage provided under the state plan does not substitute for coverage provided under group health plans, referred to as “crowd out” provisions. Over time, states have proposed, and CMS has approved, a number of different measures to prevent substitution of coverage.

⁶ 42 C.F.R. § 457.50.

⁷ *Id.*

⁸ 42 C.F.R. § 457.60.

⁹ 42 U.S.C. § 1397aa(a); 42 C.F.R. § 457.70.

¹⁰ 42 U.S.C. § 1397bb(b)(3)(C). CMS explained in the preamble to a final rule implementing SCHIP that the potential for substitution of SCHIP coverage for private coverage exists because SCHIP coverage may be less expensive than private coverage or provide better coverage than some individuals or employers could purchase with their own funds. *See State Child Health; Implementing Regulations for the State Children's Health Insurance Program*, 66 Fed. Reg. 2490, 2602 (Jan. 11, 2001) (final rule).

¹¹ 42 U.S.C. § 1397bb(c)(2).

¹² *See* 64 Fed. Reg. at 60921-23; 66 Fed. Reg. at 2601-2610.

The August 17, 2007 Letter

On August 17, 2007, CMS issued a letter to state health officials (SHO #07-001) for the stated purpose of clarifying how CMS “applies existing statutory and regulatory requirements” for states that want to extend coverage under their SCHIP programs to children in families with effective family incomes above 250 percent of the federal poverty level (FPL). Specifically, the letter indicates that it is “clarifying that the reasonable procedures adopted by States to prevent crowd-out pursuant to 42 C.F.R. 457.805 should include . . . five general crowd-out strategies with certain important components.” The five crowd out strategies identified in the letter are:

1. imposing waiting periods between dropping private coverage and enrollment in SCHIP;
2. imposing cost sharing in approximation to the cost of private coverage;
3. monitoring health insurance status at the time of application;
4. verifying family insurance status through insurance databases; and
5. preventing employers from changing dependent coverage policies that would favor a shift to public coverage.

In addition, the letter indicates that CMS “will expect” that these states incorporate the following components into their strategies to prevent substitution of coverage:

1. the cost sharing requirement under the state plan compared to the cost sharing required by competing private plans must not be more favorable to the public plan by more than 1 percent of the family income, unless the public plan’s cost sharing is set at the 5 percent family cap;
2. the state must establish a minimum of a 1-year period of uninsurance for individuals prior to receiving coverage; and
3. monitoring and verification must include information regarding coverage provided by a noncustodial parent.

The letter also indicates that CMS will seek a number of assurances from states, including an assurance that the state has enrolled at least 95 percent of the children in the state with family incomes below 200 percent of the FPL who are eligible for SCHIP or Medicaid.

According to the August 17 letter, CMS will expect states that seek to amend their SCHIP state plans and section 1115 demonstrations¹³ to cover children with effective family incomes above 250 percent of the FPL to include these specific measures. Furthermore, the letter indicates that CMS will apply the “review strategy” described in the letter to instances in which SCHIP plans and section 1115 programs already include these children. The letter indicates that states will be expected to amend their SCHIP plans or section 1115 demonstration programs in accordance with the

¹³ Section 1115 of the Social Security Act authorizes the Secretary of Health and Human Services to conduct demonstration programs likely to assist in promoting the objectives of specified programs. 42 U.S.C. § 1315; 42 U.S.C. § 1397gg(e).

provisions of the review strategy within 12 months or CMS “may pursue corrective action.”

DISCUSSION

The Review Act is intended to keep Congress informed about the rulemaking activities of federal agencies and to allow for congressional review of rules.¹⁴ The Review Act provides that before a rule can take effect, the agency promulgating the rule must submit to each House of Congress and the Comptroller General a report containing a copy of the rule; a concise general statement concerning the rule, including whether it is a major rule; and the proposed effective date of the rule.¹⁵ Among other things, the Review Act sets forth a procedure for congressional disapproval of agency rules, specifically a joint resolution of disapproval effective upon signature by the President. The Review Act provides that no determination, finding, action, or omission under the Review Act shall be subject to judicial review.¹⁶

The definition of the term “rule” in the Review Act incorporates by reference the definition in the Administrative Procedure Act (APA), with some exceptions. Our analysis of whether the August 17 letter is a rule under the Review Act thus entails determining whether it is a rule under the APA and whether it falls within any of the exceptions contained in the Review Act.¹⁷ The APA definition of rule has been said to include “nearly every statement an agency may make.”¹⁸ This definition is as follows:

¹⁴ See 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh); see also *New York v. American Electric Power Service Corp.*, Nos. 2:04 CV 1098, 2:05 CV 360, 2006 WL 1331543, at *13 (S.D. Ohio Mar. 21, 2006); *United States v. Southern Indiana Gas and Electric Co.*, No. IP99-1692-C-M/S, 2002 WL 31427523, at *3 (S.D. Ind. Oct. 24, 2002); *Texas Savings & Community Bankers Ass’n v. Federal Housing Finance Board*, No. A 97 CA 421 SS, 1998 WL 842181, at *7 (W.D. Tex. June 25, 1998).

¹⁵ 5 U.S.C. § 801(a)(1). On the date the report is submitted, the agency also must submit to the Comptroller General and make available to each House of Congress certain other documents, including a cost-benefit analysis, if any, and agency actions relevant to the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995, and any other relevant information or requirements under any other legislation or any relevant executive orders. 5 U.S.C. § 801(a)(1)(B)(i)-(iv). For rules that federal agencies identify as major rules, the Comptroller General is required under the Review Act to provide a report to the committees of jurisdiction in each House on whether the agency complied with certain procedural requirements. 5 U.S.C. § 801(a)(2)(A).

¹⁶ 5 U.S.C. § 805. A number of federal courts have concluded that an agency’s failure to submit a rule in accordance with the Review Act is not reviewable. See *American Electric Power Service Corp.*, 2006 WL 1331543, at *13; *United States v. American Electric Power Service Corp.*, 218 F. Supp. 2d 931, 949 (S.D. Ohio 2002); *Texas Savings & Community Bankers Ass’n*, 1998 WL 842181, at *7. One court has ruled that the Review Act does not preclude review of the agency’s failure to submit a rule as required by the Review Act. See *Southern Indiana Gas and Electric Co.*, 2002 WL 31427523, at *5–*6.

¹⁷ The Review Act excepts the following from its definition of rule: (1) rules of particular applicability, including a rule that approves or prescribes for future application rates, wages, prices, services, or allowances therefor, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. § 804(3). As discussed below, the letter is not a statement of particular applicability; rather, it substantially affects all states that seek to cover children with effective family incomes in excess of 250 percent of the FPL, as well

[T]he whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing[.]¹⁹

Agency statements that create binding legal norms—those that, for example, grant rights, impose obligations, or affect private interests—are rules under the APA.²⁰ These rules—usually called legislative rules—generally must be promulgated through notice and comment rulemaking procedures under 5 U.S.C. § 553. Courts have found that other agency pronouncements also are rules as defined in 5 U.S.C. § 551, even if they do not create binding legal norms and are not subject to notice and comment rulemaking requirements under section 553. For example, agency guidance documents and manuals have been held to be rules.²¹ Agency documents that clarify or explain existing legal requirements also have been held to be rules.²² Whether a particular agency pronouncement is a rule under section 551, therefore, does not turn on whether the rule is subject to notice and comment rulemaking requirements under section 553.

Legislative history of the Review Act confirms that the Review Act is intended to include within its purview almost all rules that an agency issues and is not limited to those rules that must be promulgated according to the notice and comment

as those states that already cover these children. The letter does not relate to agency management or personnel, and it does not relate to “agency organization, procedure, or practice” with no substantial affect on non-agency parties. Accordingly, we do not believe that any of these three exceptions applies to the August 17 letter.

¹⁸ *Batterton v. Marshall*, 648 F.2d 694, 700 (D.C. Cir. 1980).

¹⁹ 5 U.S.C. § 551(4).

²⁰ *Batterton*, 648 F.2d at 700-02.

²¹ See *Reno v. Koray*, 515 U.S. 50, 60–61 (1995) (internal agency guideline was a rule under the APA); *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 99–100 (1995) (provision of the Medicare Provider Reimbursement Manual was a rule under the APA); *Appalachian Power Co. v. Environmental Protection Agency*, 208 F.3d 1015, 1021–22 (D.C. Cir. 2000) (agency guidance document can be rule under the APA); *Professionals and Patients for Customized Care v. Shalala*, 56 F.3d 592, 601–02 (5th Cir. 1995) (FDA Compliance Policy Guide was a rule, but was exempt from notice and comment procedures as a statement of policy or interpretative rule).

²² See, e.g., *A.D. Transport Express, Inc. v. United States*, 290 F.3d 761, 768 (6th Cir. 2002) (order explaining agency regulation is an interpretative rule under the APA); *Guardian Federal Savings and Loan Ass’n v. Federal Savings and Loan Insurance Corp.*, 589 F.2d 658, 664 (D.C. Cir. 1978) (agency statements that clarify laws or regulations are rules under the APA).

requirements in section 553 of the APA. In his floor statement during final consideration of the bill, Representative McIntosh, a principal sponsor of the legislation, pointed out that rules subject to congressional review are not just those rules subject to APA notice and comment requirements:

Although agency interpretive rules, general statements of policy, guideline documents, and agency policy and procedure manuals may not be subject to the notice and comment provisions of section 553(c) of title 5, United States Code, these types of documents are covered under the congressional review provisions of the new chapter 8 of title 5.

Under section 801(a), covered rules, with very few exceptions, may not go into effect until the relevant agency submits a copy of the rule and an accompanying report to both Houses of Congress. Interpretive rules, general statements of policy, and analogous agency policy guidelines are covered without qualification because they meet the definition of a 'rule' borrowed from section 551 of title 5, and are not excluded from the definition of a rule.²³

Our prior opinions on the status of agency pronouncements under the Review Act reflect the breadth of the term "rule," applying a definition of the term that reaches pronouncements beyond those that require notice and comment rulemaking.²⁴

The APA definition of rule includes three elements relevant to our consideration of whether the August 17 letter is a rule: an agency statement is a rule if it is of general applicability; of future effect; and designed to implement, interpret, or prescribe law or policy. An examination of the text of the letter itself indicates that it meets these criteria. The letter is of general, rather than particular, applicability since it extends to all states that seek to enroll children with effective family incomes exceeding 250 percent of the FPL in their SCHIP programs, as well as to all states that have already enrolled such children.²⁵ In addition, it is of future effect since it concerns policy considerations for the future rather than the evaluation of past and present conduct.²⁶ Further, by its own terms, the letter purports to clarify and explain statutory and

²³ 142 Cong. Rec. H3005 (daily ed. Mar. 28, 1996) (statement of Rep. McIntosh).

²⁴ See, e.g., B-287557, May 14, 2001 ("record of decision" issued by the Fish and Wildlife Service of the Department of Interior in connection with a federal irrigation project was a rule); B-274505, September 16, 1996 (memorandum issued by Secretary of Agriculture in connection with the Emergency Salvage Timber Sale Program was a rule).

²⁵ Cf. *U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* 13 (1947) (the term "rule" includes statements of particular applicability applying either to a class or to a single person).

²⁶ See *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216 (1988) (Scalia, J., concurring) ("future effect" means that statement will have legal consequences for the future); see also *U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act* at 13-14 (rulemaking regulates the future conduct of either groups of persons or a single person and is essentially legislative in nature because it operates in the future and is primarily concerned with policy considerations, while adjudication is concerned with the determination of past and present rights and liabilities.)

regulatory requirements. The very first sentence explains that the letter “clarifies how [CMS] applies existing statutory and regulatory requirements” with regard to requests from states to extend coverage under SCHIP to children with effective family incomes above 250 percent of the FPL. The letter also purports to explain the requirements under 42 C.F.R. § 457.805 regarding state efforts to prevent substitution of coverage and the measures that states seeking to cover these populations should take to prevent substitution of coverage. In addition, the letter indicates that the requested assurances help ensure the coordination of SCHIP coverage with other coverage, thus indicating that the assurances promote the implementation of one of the statutory objectives for state plans.²⁷ In particular, it indicates that states that already have included coverage under their SCHIP programs for children with effective family incomes above 250 percent of the FPL are expected to adjust their state plans accordingly. Because the letter purports to provide an explanation of statutory and regulatory requirements and to explain how the provisions adopted effectuate both legal requirements and policy choices attendant to administration of SCHIP, the document on its face is designed to implement, interpret, or prescribe law or policy within the meaning of section 551(4) of the APA.

The history of 42 C.F.R. § 457.805, the regulation that the August 17 letter purports to clarify, supports our view that the letter is a rule. In the preamble to the proposed rule to implement SCHIP, CMS considered whether to require states to adopt a set of particular measures to prevent substitution of coverage and expressly declined to impose such a requirement. CMS concluded that, based on its interpretation of the governing statute and evidence, it did not have a basis upon which to require such measures. CMS explained its position as follows:

The other option that we considered was to require a set of specific procedures that each State would have to use to address substitution [of coverage]. We rejected this option because the statute authorizes States to design approaches to prevent substitution, not the Federal government. We also recognized that there is not substantial evidence favoring any specific approach to reduce the potential for substitution.²⁸

CMS confirmed this interpretation in a final rule.²⁹ The August 17 letter, however, explains that CMS’s experience and information derived from the operation of SCHIP

²⁷ Among the statutory provisions that the letter expressly refers to is section 2101(a) of the Social Security Act, which provides, in pertinent part:

Purpose.—The purpose of this title [XXI] is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

42 U.S.C. § 1397aa(a).

²⁸ 64 Fed. Reg. at 60921-22.

²⁹ See 66 Fed. Reg. at 2601-05.

programs have made it clear that the potential for substitution is greater at higher income levels. The letter further states that CMS will expect states to undertake five specific measures, include three components as part of those measures, and make three additional assurances in order to cover children with effective family incomes above 250 percent of the FPL under SCHIP. In this respect, the letter amounts to a marked departure from the agency's interpretation of the regulation regarding substitution of coverage in the preambles to the proposed and final rules. Accordingly, because of this new regulatory interpretation and because an agency may only change a settled interpretation of its own rules through the promulgation of an amending rule, the letter serves the same purpose as a rule.³⁰

CMS's application of the August 17 letter only serves to confirm that the letter has binding effect and is, therefore, a rule. In April 2007, the state of New York requested permission from CMS to amend its SCHIP plan to provide coverage to children with family incomes up to 400 percent of the FPL. CMS expressly relied on the August 17 letter to deny the request. In a letter dated September 7, 2007 to the state of New York, CMS stated, in part, the following:

New York has not demonstrated that its program operates in an effective and efficient manner with respect to the core population of targeted low-income children. Specifically, it has failed to provide assurances that the State has enrolled at least 95 percent of the children in the core targeted low-income child population, those with family incomes below 200 percent of the FPL. As outlined in an August 17, 2007, letter to State Health Officials, such assurances are necessary to ensure that expansion to higher income populations does not interfere with the effective and efficient provision of child health assistance.

In explaining the applicable requirements under 42 C.F.R. § 457.805, CMS went on to state additional grounds for its denial of New York's request to amend its SCHIP plan:

At the high proposed family income eligibility levels, reasonable procedures [to prevent substitution of coverage] should include a full range of procedures to discourage substitution. New York's proposal does not include procedures to prevent such substitution that include a 1-year period of uninsurance for populations over 250 percent of the FPL. Additionally, New York's proposed cost sharing has not met the requirement that cost sharing under the State plan compared to cost sharing required by competing private plans not be more favorable to the public plan by more than 1 percent of the family income, nor has the State proposed to set its cost sharing at the 5 percent family cap. . . .

³⁰ See *SBI Inc. v. Federal Communications Commission*, 414 F.3d 486, 498 (3d Cir. 2005) (if an agency's present interpretation of a regulation is a fundamental modification of a previous interpretation, the modification must be accomplished through notice and comment rulemaking); *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 629 (5th Cir. 2001) (a settled policy of an agency is binding on the agency and may be changed only through a rule); *Alaska Professional Hunters Ass'n v. Federal Aviation Administration*, 177 F.3d 1030, 1033-34 (D.C. Cir. 1999) (an agency is bound by settled interpretation given to its own regulation that the agency can change only by rulemaking).

For these reasons . . . I am unable to approve this [State Plan Amendment] for expanding coverage. This disapproval is consistent with the August 17, 2007 letter to State Health Officials discussing how these existing statutory and regulatory requirements should be applied to all States expanding SCHIP effective eligibility levels above 250 percent of the FPL.

CMS's action demonstrates that the letter represents the agency's decision to bind itself to the application of the letter's terms and to give the letter present and binding effect.³¹

By letter of February 20, 2008, we requested the views of the General Counsel of the Department of Health and Human Services (HHS) on whether the August 17 letter is a rule for purposes of the Review Act.³² The written response from the Director of the Center for Medicaid and State Operations within CMS did not address this issue. The response stated that it would be inappropriate to address legal issues related to the August 17 letter because the letter is the subject of a number of lawsuits.³³ Nevertheless, CMS indicated that the August 17 letter is a "general statement of policy that announces the course which the agency intends to follow in adjudications concerning compliance with requirements already set forth in regulations." The agency also referred us to a document prepared by the Department of Justice, which asserted that the August 17 letter was a general statement of policy.

The agency's characterization of the August 17 letter as a general statement of policy raises one issue relevant to our consideration: whether a general statement of policy is a rule under section 551(4) of the APA.³⁴ The term "general statements of policy" is not defined in the APA or in its legislative history. The Attorney General's Manual on the Administrative Procedure Act, which the United States Supreme Court has frequently referred to as an authoritative source for interpreting provisions of the

³¹ See *Appalachian Power Co.*, 208 F.3d at 1020-21 (if an agency treats a pronouncement as if it were controlling, if it bases enforcement actions on the policies in the document, and if it leads private parties or states to believe it must comply with the pronouncement's terms, it is a rule); *Public Citizen, Inc. v. United States Nuclear Regulatory Commission*, 940 F.2d 679, 682 (D.C. Cir. 1991) (where language and context of a statement are inconclusive, court will turn to agency's actual application to determine nature of agency pronouncement); *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988) (because agency used policy statement to determine regulated entities' obligations, policy statement is, therefore, a rule); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (form of a regulation is not controlling; substance and effect will determine whether agency statement is a rule).

³² See GAO, *Procedures and Practices for Legal Decisions and Opinions*, GAO-06-1064SP (Washington, D.C.: Sept. 2006), available at www.gao.gov/legal/resources.html.

³³ In documents filed in litigation, the Department of Justice has characterized the letter as an interpretative rule. See *New York v. United States Dep't of Health and Human Services*, No. 07 Civ. 08621 (S.D.N.Y. filed Oct. 4, 2007) (Def's Mem. Supp. Mot. Dismiss, p. 33).

³⁴ "General statements of policy" are expressly excepted from notice and comment rulemaking requirements under section 553 of the APA. In court filings submitted by the Department of Justice in separate litigation, HHS contends that the August 17 letter is not subject to notice and comment rulemaking requirements.

APA,³⁵ defines the term as “statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.”³⁶ A statement of policy, therefore, as the U.S. Court of Appeals for the District of Columbia Circuit has stated, announces the agency’s tentative intentions for the future, and “what the agency seeks to establish as policy.”³⁷ In this way, the general statement of policy serves a number of useful functions, including the facilitation of long range planning within the regulated industry and the promotion of uniformity in areas of national concern.³⁸

Section 551(4) includes within the meaning of rule a statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. As a device that provides information on the manner in which an agency will exercise its authority or what the agency will seek to propose as policy, a general statement of policy would appear to fit squarely within this category. Further, in discussing policy statements under the APA, courts have referred to them as rules.³⁹

Nevertheless, some court decisions seem to suggest that general statements of policy are not rules under the APA, which would raise, of course, the question whether they are rules under the Review Act.⁴⁰ The holdings of these cases did not address whether the agency pronouncements were rules for the purpose of section 551, but, instead, whether they were rules that should have been promulgated according to notice and comment rulemaking requirements under section 553 or whether they were subject to review. The better reading of these cases, in our opinion, is not that general statements of policy are not rules under 551, but that statements of policy are

³⁵ See, e.g., *Guernsey Memorial Hospital*, 514 U.S. at 99; *Georgetown University Hospital*, 488 U.S. at 218.

³⁶ *U.S. Dep’t of Justice, Attorney General’s Manual on the Administrative Procedure Act* at 14.

³⁷ See *Pacific Gas and Electric Co. v. Federal Power Commission*, 506 F.2d 33, 38 (D.C. Cir. 1974).

³⁸ *Id.*

³⁹ See, e.g., *Chrysler v. Brown*, 441 U.S. 281, 315 (1979) (“the central distinction among agency regulations found in the APA is that between ‘substantive rules’ on the one hand and ‘interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice’ on the other”); *Professionals and Patients for Customized Care*, 56 F.3d at 596 (discussing whether policy statement at issue is interpretative rule or legislative rule); *Noel v. Chapman*, 508 F.2d 1023, 1030 (2d Cir. 1975) (general statement of policy is a rule directed at agency staff on how it will perform discretionary function); *Guardian Federal Savings and Loan Ass’n*, 589 F.2d at 666 (describing test for determining whether “a rule is a general statement of policy”).

⁴⁰ See, e.g., *Sugar Cane Growers Cooperative of Florida v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002) (some agency pronouncements lack the firmness of a prescribed standard to be considered rules); *Syncor International Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997) (the primary distinction between a rule and a general statement of policy is whether the agency intends to bind itself to a legal position); *Pacific Gas and Electric Co.*, 506 F.2d at 37 (suggesting that policy statements are not rules under the APA).

not *legislative* rules because they are tentative statements of future intent and by their nature do not have the force of law.

Even if general statements of policy are not rules for purposes of section 551, however, the August 17 letter does not qualify as a general statement of policy. In determining whether a particular agency pronouncement is a general statement of policy, courts begin with the language of the document itself and the agency's own characterization of the pronouncement.⁴¹ Although courts give deference to an agency's characterization, the label that an agency puts on the exercise of its administrative power is not conclusive.⁴² In general, if the language of the pronouncement indicates that the agency's views are tentative or simply a guide as to how the agency may exercise its authority, and the agency in fact does not treat the statement as a binding norm, then the document may be a policy statement. If, however, the document, either by its terms or as applied by the agency, imposes requirements or obligations, it would not be considered a general statement of policy.

One case in particular, cited by the Department of Justice in the memorandum included in CMS's response to our request for the agency's views, provides a useful explanation of the type of language typically found in an agency general statement of policy. In *Pacific Gas and Electric Co. v. Federal Power Commission*,⁴³ the United States Court of Appeals for the District of Columbia Circuit determined that a Federal Power Commission pronouncement was a general statement of policy exempt from notice and comment rulemaking requirements. The pronouncement, styled a "statement of policy," expressed the Commission's view of how deliveries of natural gas should be prioritized during periods of shortage. The pronouncement stated that the Commission intended to follow this priority schedule unless a particular pipeline company demonstrated that a different curtailment plan (governing allocation of available supply among customers) better served the public interest. After the statement was issued, a number of parties objected to the Commission's statement, most of whom were the natural gas customers that had been assigned a low priority under the priority schedule. Among their objections was the claim that the statement was in effect a substantive rule, and not a statement of policy.

In reaching its conclusion that the statement was indeed a statement of policy, the court noted the tentative nature of the statement, as well as the Commission's acknowledgment that any particular decisions on curtailment could only be made in further proceedings. Specifically, the court found it significant that the statement indicated it was the curtailment policy that the Commission "proposes to implement" and the "plan preferred by the Commission," which "will serve as a guide in other proceedings." The Commission itself intended the statement only "to state initial guidelines as a means of facilitating curtailment planning and the adjudication of

⁴¹ *Professionals and Patients for Customized Care*, 56 F.3d at 596.

⁴² See *id.* (what the agency in fact does in relation to an agency statement is dispositive); *United States Gypsum Co. v. Muszynski*, 209 F. Supp. 2d 308, 309–10 (S.D.N.Y. 2002) (an advisory memorandum that was applied by agency as a rule was a rule).

⁴³ 506 F.2d 33 (D.C. Cir. 1974).

curtailment cases.” In addition, the statement also indicated that, although it informed the public of the types of plans the Commission might approve, there was no assurance that any such plan would be approved. Finally, the court noted that the statement indicated that during subsequent proceedings to determine particular curtailments, affected parties would have an opportunity not only to challenge the merits of the proposed plan, but to demonstrate that the plan was inappropriate in particular circumstances. In effect, the Commission statement was a starting point to frame consideration of future proposals.

If we analyze CMS’s August 17 letter using the criteria used by the court to determine that the Commission’s pronouncement was simply a statement of policy, we conclude that the letter does not meet the criteria. The August 17 letter evidences little, if any, language of tentativeness or inconclusiveness. The specific measures are not characterized as “proposals” or measures that are under development or to be implemented or adopted by later action. On the contrary, the letter sets forth specific strategies that states seeking to expand their SCHIP populations should implement as “reasonable procedures” to prevent substitution of coverage. While states previously identified and adopted one or more of the specified strategies, the August 17 letter indicates that all of them should be included as “reasonable procedures.” There is no indication that the strategies are only guidelines that may or may not be applied in subsequent proceedings. In addition, the letter contains no express mention that exceptions will be considered in particular instances. Finally, the time frame specified in the letter for states to conform to the CMS “review strategy” evidences the agency’s intention to give the letter present and binding effect:

CMS will apply this review strategy to SCHIP state plans and section 1115 demonstration waivers that include SCHIP populations, and will work with States that currently provide services to children with effective family incomes over 250 percent of FPL. We expect affected States to amend their SCHIP state plan (or 1115 demonstration) in accordance with this review strategy within 12 months, or CMS may pursue corrective action.

If the letter were simply precatory or tentative in nature, then there would be no need to establish a deadline by which states would need to implement the measures in the letter or face the possibility of a corrective action by the agency.⁴⁴ The inference to be drawn from the letter, therefore, is that states that do not conform to or adopt the measures described in the letter will likely be found to be not in compliance with SCHIP requirements.

In addition to the particular language of a statement, courts look to an agency’s actions in relation to the statement to determine whether it is a general statement of policy. As a number of courts have noted, a critical test of whether a rule is a general statement of policy is its practical effect in a subsequent administrative proceeding. In subsequent proceedings, if the agency relies solely on the pronouncement itself to

⁴⁴ *Cf. Community Nutrition Institute v. Young*, 818 F.2d 943, 947 (D.C. Cir. 1987) (agency prescribed standard from which regulated entities could obtain “exception” or risk enforcement action indicated standard was binding).

determine rights and obligations of others, the agency has treated the policy statement as if it were a binding rule, not a general statement of policy.⁴⁵ As we explained above, CMS's express reliance on the August 17 letter to deny the state of New York's request to amend its SCHIP plan leads us to conclude that the letter is not a policy statement. Our conclusion that the August 17 letter is not a general statement of policy is reinforced by our observation that it reflects a significant change in the agency's settled interpretation of 42 C.F.R. § 457.805, which policy statements by their nature do not do.⁴⁶

CONCLUSION

Based on our analysis of the August 17, 2007 letter to state health officials, it is our opinion that the letter is a rule for the purpose of the Review Act. The letter, as discussed above, is a statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy with regard to the SCHIP program. Furthermore, we do not believe that the August 17 letter comes within any of the exceptions to the definition of rule contained in the Review Act.

We express no opinion on the applicability of any other legal requirements, including, but not limited to, notice and comment rulemaking requirements under the APA, or whether the August 17 letter would be a valid interpretation of statutes or regulations. As a legal matter, the resolution of such issues is not necessary to our determination whether the August 17 letter is a rule for purposes of the Review Act.

Accordingly, given our conclusions above, and in accordance with the provisions of 5 U.S.C. § 801(a)(1), the letter must be submitted to Congress and the Comptroller General before it can take effect.

⁴⁵ See *Public Citizen, Inc.*, 940 F.2d at 682-83 (courts look to agency's actual application of statement to determine its nature if language and context of agency statement are not conclusive); *Guardian Federal Savings and Loan Ass'n*, 589 F.2d at 666 (in subsequent administrative proceeding, agency cannot claim that prior statement of policy itself resolves contested issues).

⁴⁶ See *Syncor International Corp.*, 127 F.3d at 94 (a general statement of policy does not impose, elaborate, or interpret a legal norm, but explains the agency's manner of enforcing the existing legal norm).

EXHIBIT B



Memorandum

January 10, 2008

TO: Hon. John D. Rockefeller IV
Attention: Jocelyn Moore

FROM: Morton Rosenberg
Specialist in American Public Law
American Law Division

SUBJECT: Applicability of the Congressional Review Act to a CMS Guidance Document Regarding Statutory and Regulatory Requirements to be Used in Reviewing State Requests to Extend Eligibility Under SCHIP

On August 17, 2007, the Director of the Center for Medicaid and State Operations of the Centers for Medicare and Medicaid Services (CMS) issued a letter to all state health officials "clarifying" how CMS will apply existing statutory and regulatory requirements in the review of state requests to extend eligibility under the State Children's Health Insurance Program (SCHIP) to children in families with effective family income levels above 250 percent of the Federal poverty level (FPL).

You inquire whether the CMS "clarification" letter is a rule under the Congressional Review Act (CRA) which should have been reported to the Congress and subjected to review and possible nullification by passage of a joint resolution of disapproval.¹ Our examination of the statutory scheme of the CRA, its legislative history, Government Accountability Office (GAO) opinions interpreting the scope of the coverage of the term "rule" under the Act, and analogous judicial precedents, suggests that a reviewing court is likely to hold that the legal or practical effect of the CMS document is to alter the rights, duties and obligations of non-agency parties subject to the document and that therefore the agency's action should have been submitted for review under the CRA.

¹ For a broad overview and assessment of the CRA since its passage in 1996, see Morton Rosenberg, CRS Report RL30116, *Congressional Review of Agency Rulemaking: An Update and Assessment of the Congressional Review Act After a Decade*, November 5, 2007 (CRA Report). For an in-depth discussion of procedural issues that may arise during House and Senate consideration of disapproval resolutions, see Richard S. Beth, CRS Report RL31160 *Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act*, October 10, 2001 (Archived).

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The CMS Letter

More particularly, the CMS letter explained that its experience and the information gathered in the operation of SCHIP programs indicated that procedures that had been utilized by the states to ensure SCHIP coverage under private group health plans (so called “crowd-out” procedures) were not working effectively and that it had “become clear that the potential for crowd-out is greater for higher income beneficiaries.” As a consequence of this determination, the CMS letter announced that henceforth the five crowd-out “strategies” that over the years had been identified as reasonable crowd-out prevention procedures, any one or more of which could be adopted by a state, as they considered necessary, were now mandatory in their entirety on states that expanded eligibility above the effective level of 250% of the FPL. States would now also have to incorporate three new components as part of these strategies, including requiring state establishment of a one year period of uninsurance for individuals prior to receiving aid. In addition, a state must now make “assurances” that it has enrolled at least 95% of the children in the state below 200 percent of the FPL who are eligible for SCHIP or Medicaid; that the number of children in the target population insured through private employers has not decreased by more than two percentage points over the prior five year period; and that the state is current with all reporting requirements in SCHIP and Medicaid reports relating to crowd-out requirements. The new review requirements apply to SCHIP state plans and section 1115 demonstration waivers that include SCHIP populations. CMS stated it “expected affected States to amend their SCHIP state plan (or 1115 demonstrations) in accordance with this review strategy within 12 months, or CMS will pursue corrective action” to effect compliance with the CMS guidance.

Reaction to the CMS Letter

The CMS letter raised immediate concerns among some Members of Congress, certain states and with child health interest groups that the new conditions imposed would effectively make it difficult if not impossible, for states to cover uninsured children.² Proponents of the CMA action counter that it clarifies existing law, preserves SCHIP for the core population it was intended to serve, deters further erosion of private coverage, and ensures that states are moving forward on meeting the basic goals of the program.³

A SCHIP reauthorization bill, H.R. 976, addressing the source of the concerns raised by the CMS letter, was sent to the President and was vetoed on October 18. A modified version of H.R. 976, H.R. 3963, was sent to the President who again vetoed it on November 12. No action on the second veto has been taken yet.⁴ On September 7, 2007, the Acting Administrator of CMS denied New York State’s state plan amendment (SPA) which would increase the financial eligibility standard for its separate SCHIP program from its current effective family income eligibility level to or below 400 percent of the FPL. The SPA also

² See, e.g. Cindy Mason and Michael Odeh, “Moving Backward: Newly Imposed Limits on States’ Ability to Cover Children,” Center for Children and Families, Georgetown University Health Policy Institute (August 30, 2007) accessible at <http://ccf.georgetown.edu/pdfs/cmsdirective.pdf> (Moving Backward).

³ See, e.g. Nina Owrharenko, “The Administration’s SCHIP Regulations: A Sound Prescription,” Web Memo No. 1591, August 27, 2007, accessible at www.heritage.org/research/healthcare/wm15911cfm.

⁴ See CRS Report RS22746, “SCHIP: Differences between H.R. 3963 and H.R. 976,” by Evelyn P. Baumrucker, et al.

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proposed to implement a six month waiting period of prior uninsurance for children with family incomes above 250 percent of the FPL with certain limited exceptions. The denial is the first to rely on the CMS letter. CMS held that New York had “failed to provide assurances that the state had enrolled at least 95 percent of the children in the core targeted low-income child population, those with family incomes below 200 percent of the FPL. In the absence of such assurances, I cannot conclude that New York is effectively and efficiently using available resources to serve that core population, such that expansion to higher income levels would not divert resources from serving the core population.” The CMS Director also found unreasonable New York procedures for deterring crowd-out by having a six month rather than a one year uninsurance period for populations over 250 percent of the FPL as required by the August 2007 CMS letter.

On October 4, 2007, New York, joined by Illinois, Maryland, and Washington, filed suit in Federal district court in Southern District of New York challenging the validity of the CMS letter on the grounds that it “constituted illegal rulemaking not in conformance with applicable requirements of the Administrative Procedure Act,” and HHS’s published rulemaking policy; that “the requirements it imposed are in excess of the authority vested in the Secretary of HHS under applicable law;” and that “it imposes requirements that are not set forth in statute or codified regulations... .”⁵ Finally, on November 29, 2007, CMS announced that it had approved amendments to Wisconsin’s SCHIP (Badger Care) that would insure children in families of four making up to 250 percent of the FPL. Wisconsin also agreed to abide by CMS letter’s longer uninsurance period.

The New York rejection and its lawsuit, and the apparent compromise by Wisconsin, underline the potentially large direct impact the CMS letter may have. Statistics from the Center for Children and Families of the Georgetown Health Policy Institute indicate that as of August 1, 2007, 19 states (including the District of Columbia) already have income eligibility thresholds above 250 percent of the FPL and that eight states have adopted, but not yet implemented, such eligibility thresholds. Also, four other states have income eligibility thresholds at or slightly below 250 percent of the FPL but apply deductions when computing eligibility.⁶ As a result, these states may see some children lose coverage in order to comply with the CMS letter’s August 2008 deadline.⁷

The number of states that currently exceed the new 250 percent of FPL eligibility threshold is arguably reflective of the policy of flexibility that prevailed since the adoption of the current rulemaking scheme in 2001.⁸ The Statement of Bases and Purpose accompanying and explaining the 2001 final rule makes it clear that many rigid standards in the Notice of Proposed Rulemaking were abandoned after consideration of public comments. The crowd-out procedure language at 42 C.F.R. § 457.805, relied upon by CMS as authority for the more stringent guidance restrictions here in question, simply requires that “[t]he state plan must include a description of reasonable procedures to ensure that health benefits coverage provided under the state plan does not substitute for coverage provided under group

⁵ Complaint, *State of New York et al. v. U.S. Department of Health and Human Services*, Case no. 07-CIV-8621, filed October 4, 2007.

⁶ For instance, by deducting income used to pay for child care expenses.

⁷ See, *Moving Backward*, *supra* n.2.

⁸ See 66 Fed. Reg. 2490, 2493, 2602-2610 (January 11, 2001).

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health plans as defined at section 457-10.” The introduction to the 2001 rules’ preamble explains:

Due to a general lack of evidence of the existence of substitution below 200 percent of the FPL and the significant number of comments received on this subject, we have revised the final rule to clarify our policy related to substitution. The preamble to the final rule clarifies that for coverage provided other than through premium assistance programs, we will no longer require a substitution prevention strategy for families with incomes below 250 percent of the FPL. Instead, States will be required to monitor the occurrence of substitution below 200 percent of the FPL. Between 200 and 250 percent of the FPL, we will work with States to develop procedures, in addition to monitoring, to prevent substitution that would be implemented in the event that an unacceptable level of substitution is identified. Above 250 percent of the FPL, States must have a substitution prevention mechanism in place, however we encourage States to use other strategies than waiting periods.

For States wishing to utilize premium assistance programs, we have revised the final rule to provide additional flexibility. While we have retained the 6-month waiting period without group health plan coverage, States have flexibility to include a number of exceptions for circumstances such as involuntary loss of coverage, economic hardship, and change to employment that does not offer dependent coverage. We have also removed the requirement for States to demonstrate an employer contribution of at least 60 percent when providing coverage through premium assistance programs. Rather, we have clarified that States must demonstrate cost-effectiveness of their proposals by identifying a minimum contribution level and providing supporting data to show that the level is representative of the employer-sponsored insurance market in their State.

Finally, the final rule provides that the Secretary has discretion to reduce or waive the minimum period without private group health plan coverage.⁹

The Preamble discussions with respect to the need for flexibility and working with the states with respect to individualizing crowd-out procedures fleshes out the introductory remarks:

Our review of States’ March 31, 2000 evaluations indicated that in those States with data on substitution of private coverage with SCHIP coverage, there was little evidence that substitution was as great an issue as initially anticipated. However, because of the current lack of conclusive data around the level of substitution which may be occurring below 200 percent of FPL, we maintain that monitoring of substitution of coverage in SCHIP is critical.

As noted above, we have revised the policy stated in the preamble to the NPRM regarding substitution procedures relating to SCHIP coverage provided outside of programs that offer premium assistance for coverage under group health plans as follows:

- States that provide coverage to children in families at or below 200 percent of FPL must have procedures to monitor the extent of substitution of SCHIP coverage for existing private group health coverage, as was the

⁹ 66 Fed. Reg. at 2493.

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policy for such coverage provided to families under 150 percent of FPL proposed in the preamble to the NPRM.

- At a minimum, States that provide coverage to children in families with incomes over 200 percent of FPL should have procedures to evaluate the incidence of substitution of SCHIP coverage for existing private group health coverage. In addition, States offering coverage to children in families over 200 percent of FPL must identify in their State plans specific strategies to limit substitution if monitoring efforts show unacceptable levels of substitution. States must monitor the occurrence of substitution and determine a specific trigger point at which a substitution prevention mechanism would be instituted, as described in the State plan.
- For coverage above 250 percent of the FPL, because evidence shows that there is a greater likelihood of substitution at higher income levels, States must have substitution prevention strategies in place, in addition to monitoring.

Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. States may submit amendments to their State plans if they would like to modify their current policies in light of the policies discussed here. We plan to work closely with States to develop appropriate substitution strategies, monitoring tools, and trigger mechanisms. As part of monitoring for substitution of coverage, States should also study the extent to which anti-substitution policies require children who have lost group health coverage through no fault of their own or their employer to wait to be enrolled in SCHIP. To the extent that monitoring finds that such children are forced to go without coverage, States should consider adjustments to their substitution prevention policies that permit exceptions for children who should not be the target of such policies. We will continue to ask States to assess their substitution prevention procedures in their annual reports.

Finally, we note that because the regulatory text at §457.805 required that the State plan include reasonable procedures to prevent substitution and made no distinction for eligibility levels for coverage under State plans, we have not revised the regulation text. It is consistent with our revised policy.¹⁰

* * *

We agree that State's substitution prevention efforts should be considered in the context of the entire State plan with consideration given to a State's particular needs and goals. To this end, we have retained a flexible regulatory requirement regarding substitution and indicated that HCFA will incorporate additional flexibility in its plan review process.¹¹

* * *

As stated above, periods of uninsurance will not be required unless coverage is provided via premium assistance through group health plans, coverage is provided to children with significantly higher income levels, or substitution has been identified as a problem in the State.¹²

* * *

As indicated above, outside of premium assistance programs, States have broad discretion to develop substitution prevention policies that best serve their particular

¹⁰ *Id.* at 2603.

¹¹ *Id.* at 2604.

¹² *Id.*

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populations. States that choose to retain or impose periods of uninsurance are encouraged to include exceptions that help prevent the imposition of undue hardship under a range of circumstances, including loss of insurance through no fault of the family, extreme economic hardship, death of a parent, etc.¹³

As is discussed more fully below, substantial departures from these apparent understandings may be seen by a reviewing court as requiring adherence to the notice and comment process required by Section 553 of the Administrative Procedures Act.

Congressional Review of Agency Rules

The congressional review mechanism, codified at 5 U.S.C. §§ 801-808, and popularly known as the Congressional Review Act (CRA), requires that all agencies promulgating a covered rule must submit a report to each House of Congress and to the Comptroller General (CG) that contains a copy of the rule, a concise general statement describing the rule (including whether it is deemed to be a major rule), and the proposed effective date of the rule. A covered rule cannot take effect if the report is not submitted.¹⁴ Each House must send a copy of the report to the chairman and ranking minority member of each jurisdictional committee.¹⁵ In addition, the promulgating agency must submit to the CG (1) a complete copy of any cost-benefit analysis; (2) a description of the agency's actions pursuant to the requirements of the Regulatory Flexibility Act and the Unfunded Mandates Reform Act of 1995; and (3) any other relevant information required under any other act or executive order. Such information must also be made "available" to each House.¹⁶

Section 804(3) adopts the definition of "rule" found at 5 U.S.C. § 551(4) which provides that the term rule "means the whole or part of an agency statement of general . . . applicability and future effect designed to implement, interpret, or prescribe law or policy."¹⁷ The legislative history of Section 551(4) indicates that the term is to be broadly construed: "The definition of rule is not limited to substantive rules, but embraces interpretive, organizational and procedural rules as well."¹⁸ The courts have recognized the breadth of the term, indicating that it encompasses "virtually every statement an agency may make,"¹⁹ including interpretive and substantive rules, guidelines, formal and informal statements, policy proclamations, employee manuals and memoranda of understanding, among other

¹³ *Id.*

¹⁴ 5 U.S.C. § 801(a)(1)(A).

¹⁵ 5 U.S.C. § 801(a)(1)(C).

¹⁶ 5 U.S.C. § 801(a)(1)(B).

¹⁷ 5 U.S.C. § 804(3) excludes from the definition "(A) any rule of particular applicability, including a rule that approves or prescribes for the future rates, wages, prices, services, or allowance therefore, corporate or financial structures, reorganizations, mergers, or acquisitions thereof, or accounting practices or disclosures bearing on any of the foregoing; (B) any rule relating to agency management or personnel; or (C) any rule of agency organization, or practice that does not substantially affect the rights or obligations on non-agency parties."

¹⁸ Attorney General's Manual on the Administrative Procedure Act 13 (1948).

¹⁹ *Avoyelles Sportsmen's League, Inc. v. Marsh*, 715 F.2d 897 (5th Cir. 1983).

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types of actions.²⁰ Thus a broad range of agency action is potentially subject to congressional review.

The drafters of the congressional review provision arguably adopted the broadest possible definition of the term “rule” when they incorporated § 551(4) of the APA. As just indicated, the legislative history of § 551(4) and the case law interpreting it make clear that it was meant to encompass all substantive rulemaking documents — which may include policy statements, guidances, manuals, circulars, memoranda, bulletins and the like — which as a legal or practical matter an agency wishes to make binding on the affected public.

The legislative history of the CRA²¹ emphasizes that by adoption of the § 551 (4) definition of the term “rule”, the review process would not be limited only to coverage of rules required to comply with the notice and comment provisions of the APA or any other statutorily required variations of notice and comment procedures, but would rather encompass a wider spectrum of agency activities characterized by their effect on the regulated public: “The committee’s intent in these subsections is . . . to include matters that substantially affect the rights or obligations of outside parties. The essential focus of this inquiry is not on the type of rule but on its effect on the rights and obligations of non-agency parties.”²² The drafters of the legislation indicated their awareness of the practice of agencies avoiding the notification and public participation requirements of APA notice-and-comment rulemaking by utilizing the issuance of other documents as a means of binding the public, either legally or practically,²³ and noted that it was the intent of the legislation to subject just such documents to congressional scrutiny:

The committees are concerned that some agencies have attempted to circumvent notice-and-comment requirements by trying to give legal effect to general statements of policy, “guidelines,” and agency policy and procedure manuals. The committees admonish the agencies that the APA’s broad definition of “rule” was adopted by the authors of this legislation to discourage circumvention of the requirements of chapter 8.²⁴

During floor consideration of the CRA, Representative McIntosh, a principal sponsor of the legislation, emphasized the importance that the effect on private parties was to have in determining what is a covered rule:

²⁰ See, e.g., *Chem Service, Inc. v. EPA*, 12 F.3d 1256 (3d Cir. 1993)(memorandum of understanding); *Caudill v. Blue Cross and Blue Shield of North Carolina*, 999 F.2d 74 (4th Cir. 1993)(interpretative rules); *National Treasury Employees Union v. Reagan*, 685 F.Supp 1346 (E.D. La 1988)(federal personnel manual letter issued by OPM); *New York City Employment Retirement Board v. SEC*, 45 F.3d 7 (2d Cir. 1995)(affirming lower court’s ruling that SEC “no action” letter was a rule within § 551(4)).

²¹ Joint Explanatory Statement of House and Senate Sponsors, 142 Cong. Rec. E 571 (daily ed. April 19, 1996; 142 Cong. Rec. S 3681 (daily ed. April 18, 1996).

²² Join Explanatory Statement of House and Senate sponsors, *supra* n.21, at E 579, S 3687.

²³ This practice has been long recognized and criticized in administrative law commentaries. See, e.g., Robert A. Anthony, Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like — Should Federal Agencies Use Them To Bind The Public? 41 Duke L.J. 1311 (1992). See also, General Accounting Office, Federal Rulemaking: Agencies Often Published Final Actions Without Proposed Rules, GAO/GGD-98-126 (August 1998).

²⁴ Join Explanatory Statement of House and Senate sponsors, *supra* n.21, at E 578, S 3687.

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Pursuant to section [804(3)(C)], a rule of agency organization, procedure, or practice, is only excluded if it “does not substantially affect the rights or obligations of nonagency parties.” The focus of the test is not on the type of rule but on its effect on the rights or obligations of nonagency parties. A statement of agency procedures or practice with a truly minor, incidental effect on nonagency parties is excluded from the definition of the rule. Any other effect, whether direct or indirect, on the rights and obligations of nonagency parties is a substantial effect within the meaning of the exception. Thus, the exception should be read narrowly and resolved in favor of nonagency parties who can demonstrate that the rule will have a non-trivial effect on their rights and obligations.²⁵

Representative McIntosh also pointed out that rules subject to congressional review are not the same as those subject to APA notice and comment requirements:

All too often, agencies have attempted to circumvent the notice and comment requirements of the Administrative Procedure Act by trying to give legal effect to general policy statements, guidelines, and agency policy and procedure manual. Although agency interpretative rules, general statements of policy, guideline documents, and agency and procedure manual may not be subject to the notice and comment provisions of section 553(c) of title 5, United States Code, these types of documents are covered under the congressional review provisions of the new chapter 8 of title 5.

Under section 801(a), covered rules, with very few exceptions, may not go into effect until the relevant agency submits a copy of the rule and an accompanying report to both Houses of Congress. Interpretive rules, general statements of policy, and analogous agency policy guidelines are covered without qualification because they meet the definition of a “rule” borrowed from section 551 of Title 5, and are not excluded from the definition of rule.²⁶

To date, at least eight agency failures to report agency actions have come to the attention of committee chairmen and Members and were referred to the Comptroller General for determinations whether they were covered rules. In five of the eight cases the Comptroller General determined the action documents to be reportable rules.²⁷ Two are pertinent to the instant matter.

In Opinion Number B-281575 (January 20, 1999), GAO advised that an “Interim Guidance for Investigating Title VI Administrative Complaints Challenging Permits” issued by the Environmental Protection Agency (EPA) was a reportable rule. EPA had argued that the rule fell within the exception of 5 U.S.C. § 804 (3)(C) as a “rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.” The GAO General Counsel noted that “it is the substance of what EPA has purported to do and has done which is decisive.” Here, the General Counsel found that the Interim Guidance established procedures that departed from existing rules, giving the recipients of a complaint rights they did not have under those rules, and held “they clearly alter the existing regulation and give significant rights they did not previously possess for obtaining dismissal of a complaint. In this respect these new steps meet the elements of a

²⁵ 142 Cong. Rec. H3005 (daily ed. March 28, 1996).

²⁶ *Id.*

²⁷ See CRA Report, *supra* n. 1, at 25-26.

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substantive rule: they affect the rights and duties of the recipient, the complainant, and the affected populations; they will have future effect and they change the existing regulation.”

In Opinion Number B-286338 (October 17, 2000) the issue involved the Farm Credit Administration’s (FCA) establishment of a National Charter Initiative which would accept applications for national charters that would remove regulatory geographic barriers imposed on Farm Credit System banks. Geographic jurisdiction limitations had been a historic policy of the FCA which it attempted to alter in a 1998 notice-and-comment rulemaking. The proposal was dropped from the final rule but FCA attempted to accomplish this purpose through its so-called National Charter Initiative. The GAO General Counsel rejected the claim that the application process set up by the Initiative was adjudicatory in nature, finding that since the express purpose of the Initiative was to change the geographic limitation policy, it was unrelated to any particular institution’s application. Rather, the General Counsel found, it was of general applicability, future effect, and prescribed a change in policy that would have a substantial effect on non-agency parties and thus was a reportable rule.

In an analogous manner, the courts have looked behind the label an agency has given a particular action document to ascertain the practical effect it has had on non-agency parties. Where the courts have discerned that the agency document has substantively changed the rights, duties and obligations of regulated persons, they have held the agency action invalid for failure to comply with the APA’s notice and comment requirements. For example, in *Appalachian Power Co. v. EPA*,²⁸ the appeals court dealt with a claim by electrical power companies and trade associations that a “guidance” document allegedly imposed unauthorized requirements on states in connection with their operating permit purposes. The court found that the document was a final binding decision of the agency subject to judicial review, the guidance broadened the underlying agency rule and that its promulgation was impermissible absent notice and comment rulemaking procedures. The court held that: “If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe it will declare permits invalid unless they comply with the terms of the document, then the agency’s document is for all practical purposes ‘binding.’”

Similarly, in *Chamber of Commerce of the U.S. v. Department of Labor*,²⁹ OSHA had issued a directive stating that employees in certain industries that participated in a “cooperative compliance program” would have significantly reduced risk of being subject to an inspection. The cooperative program included some requirements that “exceed[ed] those required by law.” The appeals court concluded that: “In practical terms, the [DOL] Directive places the burden upon those employers that fail to join [the program], and will have a substantial impact upon all employers within its purview—including those that acquiesce in the agency’s use of ‘leverage’ against them.”³⁰

²⁸ 208 F.3d 1015, 1020-23 (D.C. Cir. 2000).

²⁹ 174 F.3d 206, 211-13 (D.C. Cir. 1999).

³⁰ See also, *National Family Planning and Reproductive Health Assoc. v. Sullivan*, 979 F. 2d 227, 229 (“The new ‘Directives’ neither clarify nor explain the previous regulation, which was adopted by notice and comment rulemaking, but instead effectively amend the 1988 regulations to
(continued...)”)

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Conclusion

Our analysis of the statutory scheme of the CRA, its legislative history, and opinions of the General Counsel of GAO, indicates that the framers of the congressional review provision were concerned with then prevalent agency actions that had the practical effect of imposing binding norms on non-agency parties without being promulgated in conformance with requirements of notice and comment rulemaking, and therefore adopted a broad definition of the term “rule” that would capture such actions for congressional review. The rulings of numerous appellate courts recognizing the invalidity of such actions supports the CRA’s history and the GAO interpretations. The courts have also indicated that the past practice of an agency in implementing a rulemaking may be looked at for insight as to the understanding and reliance regulated parties and beneficiaries have placed on such past agency practices. In such instances, the courts have held that an abrupt change of course requires a rulemaking to substantively alter those practices and relied upon interpretations. In this instance, CMS practice under the 2001 crowd-out rules arguably has become a “binding norm,” and that changing such practice is an action that is covered by the CRA that may not be effectuated until it is reported to Congress and the Comptroller General.

³⁰ (...continued)

significantly alter its meaning, as previously interpreted and enforced by HHS and upheld by the Supreme Court in *Rust v. Sullivan* [500 U.S. 173(1991)].”). See also, *Davidson v. Glickman*, 169 F.3d 996 (5th Cir. 1999); *Snyder Intl. v. Shalala*, 127 F.,3d. 90 (D.C. Cir. 1997); *Paralyzed Veterans of America v. D.C. Area L.P.*, 117 F. 3d 579, 587 (D.C. Cir. 1997); *Hoctor v. U.S. Department of Agriculture*, 82 F.3d. 165 (7th Cir. 1996). See severally, Jefferey S. Lubbers, “A Guide to Federal Agency Rulemaking,” pp.73-104 (4th Ed. 2006).